

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Gayo-Fung et al.

Confirmation No.: 6368

Application No.: 10/731,666

Group Art Unit: 1614

Filed: December 8, 2003

Examiner: Gembeh, Shirley V.

For: COMPOUNDS AND METHODS FOR
MODULATION OF ESTROGEN
RECEPTORS

Attorney Docket No.: 10624-136-999
(CAM No.: 700755-999135)

**REQUEST FOR RECONSIDERATION OF PATENT
TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)**

MAIL STOP PATENT EXT.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Patent Term Adjustment as set forth in the Issue Notification issued on September 24, 2008, Applicants hereby request reconsideration of the Patent Term Adjustment under 37 C.F.R. § 1.705(d). The basis for the request and the provision for the required fee is provided herein.

REMARKS

Applicants received a Notice of Allowance and Fee(s) Due ("Notice") dated July 22, 2008 from the U.S. Patent and Trademark Office ("PTO") in connection with the above-identified application No. 10/731,666 (hereinafter "the '666 application"). Accompanying the Notice was a Determination of Patent Term Adjustment under 35 U.S.C. 154 (b), which indicated that the patent term adjustment to date was 256 days for the '666 application. The '666 application issued as U.S. Patent No. 7,435,729 B2 (hereinafter "the '729 patent") on October 14, 2008. The front page of the '729 patent indicates that the patent term adjustment has been revised to be 435 days.

Applicants hereby respectfully request reconsideration of the revised patent term adjustment indicated on the front page of the '729 patent. Specifically, Applicants believe that the patent term adjustment should be increased by 423 days to a total of **858** days.

An application for patent term adjustment under 37 C.F.R. § 1.705(d) must comply with the requirements of 37 C.F.R. §§ 1.705(b)(1)-(2). Accordingly, an application for patent term adjustment under 37 C.F.R. § 1.705(d) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
 - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
(B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be **\$200.00**. Applicants are authorizing payment of the required fee via EFS-web. Should the PTO determine that any additional fee is required, please charge the required fee to Jones Day Deposit Account No. 50-3013.

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.705(b)(2), Applicants submit the following statement of facts in support of this application:

- (i) The correct patent term adjustment calculated under 37 C.F.R. § 1.702(a) is 858 days, which is the delay by the PTO under 37 C.F.R. §§ 1.702(a)(1), 1.702(a)(2) and 1.702(b) of 1173 (with overlap between

1.702(a)(2) and 1.702(b) of 74 days removed) minus 241 days Applicant delay under 37 C.F.R. § 1.704.

The basis for the adjustment is as follows:

1. Delay by the PTO under 37 C.F.R. § 1.702(a)(1): 37 C.F.R. § 1.702(a)(1) provides that the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the PTO to mail at least one of (i) a notification under 35 U.S.C. § 132 or (ii) a notice of allowance under 35 U.S.C. § 151, not later than fourteen months after the date on which the application was filed under 35 U.S.C. § 111(a) or fulfilled the requirements of 35 U.S.C. § 371 in an international application. *See* 37 C.F.R. § 1.702(a)(1). As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date on which the '666 application fulfilled the requirements of 35 U.S.C. § 371. The '666 application fulfilled the requirements of 35 U.S.C. § 371 on December 8, 2003. Accordingly, a notification under 35 U.S.C. § 132 was due by February 8, 2005. However, the first notification under 35 U.S.C. § 132 (a Non-Final Rejection) was mailed by the PTO on March 7, 2006, which is a delay of 392 days.
2. Delay by the PTO under 37 C.F.R. § 1.702(a)(2): 37 C.F.R. § 1.702(a)(2) provides that the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the PTO to respond to a reply under 35 U.S.C. 132 or to an appeal taken under 35 U.S.C. 134 not later than four months after the date on which the reply was filed or the appeal was taken. *See* 37 C.F.R. § 1.702(a)(1). As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to respond to a reply under 35 U.S.C. 132 within four months after the date on which the reply was filed. A reply under 35 U.S.C. 132 was filed in connection with the '666 application on July 7, 2006. Accordingly, response by the PTO was due by November 11, 2006. However, a response (Non-Final

Rejection) was mailed by the PTO on February 20, 2007, which is a delay of 105 days.

3. Delay by the PTO under 37 C.F.R. § 1.702(b): 37 C.F.R.

§ 1.702(b) provides that the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the PTO to issue a patent within three years of the actual filing date of the application. *See* 37 C.F.R. § 1.702(b). The PTO failed to issue the '666 application within three years of the actual filing date. The actual filing date of the '666 application was December 8, 2003.

Accordingly, the '666 application should have issued by December 8, 2006. However, the '666 application issued on October 14, 2008, which is a delay of 676 days.

- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:

1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e): An adjustment is sought under 37 C.F.R. § 1.703(a), which provides that the period of adjustment under 37 C.F.R. § 1.702(a) is the sum of the following periods:

- (1) The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. § 111(a) or fulfilled the requirements of 35 U.S.C. § 371 in an international application and ending on the date of mailing of either an action under 35 U.S.C. § 132, or a notice of allowance under 35 U.S.C. § 151, whichever occurs first.

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.702(a)(1) for the period beginning February 8, 2005 and ending March 7, 2006. Applicant confirms that this period consists of 392 days.

- (2) The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply under § 1.111 was filed and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.702(a)(2) for the period beginning July 7, 2006 and ending February 20, 2007. Applicant confirms that this period consists of 105 days.

2. Adjustment under 37 C.F.R. § 1.703(b): An adjustment is sought under 37 C.F.R. § 1.703(b), which provides that the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the applications was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued.
- (1) The actual filing date of the '666 application was December 8, 2003. Accordingly, the '666 application should have issued by December 8, 2006. However, the '666 application issued on October 14, 2008, which is a delay of 676 days.
3. Adjustment under 37 C.F.R. § 1.703(f): As discussed in section (i) above, Applicants believe that the total delay by the PTO under 37 C.F.R. §§ 1.702(a) and (b) amounts to 1173 days. As discussed in section (iv) below, Applicants believe that the total delays attributable to Applicants under 37 C.F.R. § 1.704 amount to 241 days. Applicants believe that the total period of adjustment due under 37 C.F.R. § 1.703(f) is **858 days**, which is the sum of the periods by the PTO calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 1173 days), minus the extent that the periods under 1.702(a) and (b) are overlapping (*i.e.*, from December 8, 2006 to February 20, 2007, which is 74 days), less the sum of the periods calculated under Section 1.704 (*i.e.*, 241 days).

Applicants respectfully submit that the PTO miscalculated the total delay by the PTO under 37 C.F.R. §§ 1.702(a)(1)-(2) and (b) as being 676 days. In *Wyeth et al. v. Dudas* (hereinafter *Wyeth*) the District Court for the District of Columbia clarified the meaning of 37 C.F.R. § 1.703(f). See Memorandum Opinion and Order, No. 07-1492, Doc No. 27 (D.D.C. September 30, 2008). In *Wyeth*, plaintiff Wyeth complained that the PTO had miscounted and deprived them of a portion of the extended term. The Court agreed with Wyeth, holding that “the only way that periods of time can ‘overlap’ is if they occur on the same day [and thus, if] an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap.” Consequently, under *Wyeth*, the delay under 37 C.F.R. § 1.702(a)(1)-(2) does not overlap the delay under 37 C.F.R. § 1.702(b) for the ’666 application, and therefore the total delay under 37 C.F.R. § 1.702 for the adjustment should be a summation of the delays under 37 C.F.R. § 1.702(a)(1)-(2) and 37 C.F.R. § 1.702(b), or 1173 days (the sum of 497 and 676 days).

- (iii) The ’666 application is not subject to a terminal disclaimer.
- (iv) The circumstances during the prosecution of the ’666 application that constitute a failure to engage in reasonable efforts to conclude processing or examination of the ’666 application as set forth in 37 C.F.R. § 1.704 are believed to consist of the following:
 - 1. 69 days due to Applicants’ filing of executed Declarations on August 24, 2004 in response to the Notice to File Missing Parts of Nonprovisional Application mailed on March 16, 2004.
 - 2. 30 days due to Applicants’ filing of a response on July 7, 2006 to the Non-Final Rejection mailed on March 7, 2006.
 - 3. 82 days due to Applicants’ filing of a response on August 10, 2007 to the Non-Final Rejection mailed on February 20, 2007.

4. 60 days due to Applicants' filing of a response on April 2, 2008 to the Non-Final Rejection mailed on November 2, 2007.

Accordingly, Applicants' believe that the delays attributable to Applicants under 37 C.F.R. § 1.704 total 241 days.

CONCLUSION

In summary, the total adjustment under 37 C.F.R. § 1.702(a) is 497 days, the total adjustment under 37 C.F.R. § 1.702(b) is 676 days, the total overlap between the periods under 37 C.F.R. §§ 1.702(a) and (b) is 74 days, the total delays attributable to Applicants under 37 C.F.R. § 1.704 are 241 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be **858 days**. Accordingly, Applicants respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 858 days.

In accordance with 37 C.F.R. § 1.705(d), this application for patent term adjustment is being filed no later than two months within the date the '729 patent issued. Entry of this Request for Reconsideration of Patent Term Adjustment, grant of the request and publication of the new Patent Term Adjustment is respectfully requested.

Respectfully submitted,

Anthony M. Insogna, Reg. No. 35,203
By: Michael J. Bruner, Reg. No. 47,458

Date: November 21, 2008

By: Michael J. Bruner (Reg. No. 47,458)
JONES DAY
222 East 41st Street
New York, New York 10017
(404) 581-8614

For: Anthony M. Insogna (Reg. No. 35,203)
JONES DAY
12265 El Camino Real, Suite 200
San Diego, California 92130
(858) 314-1130